REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein; does not raise any new issue requiring further search and/or consideration, because the amendments amplify issues previously discussed throughout prosecution; relates to matters of form rather than substance, because the added language was already present in the claims; no new claims are added; and places the application in better form for an appeal should an appeal be necessary. The Amendment is necessary and was not earlier presented because it is made in response to arguments raised in the final rejection. Entry of the Amendment, reexamination, and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are thus respectfully requested.

1. Status of the Claims

The status of the claims prior to amendment is as follows:

Claims pending: Claims 17-46

Claims cancelled: Claims 1-16

Claims withdrawn: Claims 32-38

Claims rejected: Claims 17-31 and 39-46

The Office withdraws claims 32-38 from consideration, alleging that claims 32-38 are drawn to non-elected subject matter. Office Action, page 2. Applicants note that claims 32-38 are entitled to be rejoined once claims 17-31 and 39-46 are found allowable.

After entry of the present amendments, Applicants have amended claim 39 to more precisely recite the subject matter. Support of claim amendments can be found at least, for example, from originally filed claims. Applicants submit that no prohibited new matter is introduced by entry of the present amendments.

Cancellation of and amendments to the claims have been made without prejudice to or disclaimer of the subject matter contained therein. Applicants reserve the right to file a continuation and/or divisional on any subject matter canceled by way of amendment.

2. Priority

Applicants note the Office's acknowledgement on page 2 of the Office Action that the certified priority documents submitted January 23, 2006, has been received. Confirmation of acceptance is respectfully requested with the Office's next communication for clarification, because the Office Action Summary does not reflect receipt of the certified copy of the priority application.

3. Drawings

Applicants appreciate the Office's acknowledgement on page 2 of the Office Action that the drawings filed January 23, 2006, have been received and entered. Confirmation of their acceptance without defect is respectfully requested with the Office's next communication for clarification of their status, because the Office Action Summary does not reflect their acceptance.

4. Withdrawn Rejections

Applicants note with appreciation that the Office withdraws the following rejections:

1) the indefiniteness rejection of claims 32-38;

2) the rejection of claims 32-46 under 35 U.S.C. § 101;

3) the enablement rejection of claims 17-46; and

4) the obviousness rejection of claims 32-38.

Office Action, page 2.

5. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 39-46 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Without acquiescing as to the merits of the Office's rejection, Applicants amends claim 39 to recite "a method of preparing a food or drink having an effect of ameliorating liver diseases associated with hepatopathy." The Office's rejection is thus moot. Applicants respectfully request withdrawal of the rejection, and allowance of the claims.

6. Rejection of the Claims Under 35 U.S.C. § 103(a)

The Office maintains the rejection of claims 17-31 and 39-46 under 35 U.S.C. § 103(a) as allegedly obvious over **Bistrian** et al., U.S. Patent No. 5,320,846 [hereinafter "Bistrian"] and **Akimoto** et al., U.S. Published Application No. 2004/0171127 [hereinafter "Akimoto"].

Bistrian allegedly teaches administering a total enteral nutritional diet or a dietary supplement to treat patients with clinical disorders. Office Action, page 4. The patient allegedly may suffer from cancer, a clinical liver dysfunction or trauma such as ischemia, trauma, sepsis, malnutrition, liver surgery, hepatitis, or liver transplant. *Id.* The diet allegedly consists essentially of a lipid source, a protein source, a vitamin source, a carbohydrate source, and a mineral source. The lipid source allegedly contains essential fatty acids such as omega-9 fatty acid. *Id.* Akimoto allegedly teaches preparing a fat comprising a triglyceride with an omega-9 fatty acid moiety. *Id.*, at 4-5. The fat allegedly may be used in foods and pharmaceuticals for treating and preventing arteriosclerosis, thrombosis, and cancer. *Id.*, at 5.

The Office argues that it would have been obvious to combine the teachings of Bistrian and Akimoto to produce a method of ameliorating liver diseases by administering an omega-9 unsaturated fatty acid. *Id.* The Office further relies on *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072 (C.C.P.A. 1980) ("It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose."). Office Action, page 5. The same purpose allegedly refers to (1) the hepatitis-treating effect by the Bistrian's composition, and (2) the anti-inflammatory function of omega-9 fatty acids according to Akimoto. *Id.*, at 8-9. The Office alleges, "[h]epatitis is an inflammation of the liver, therefore, to a patient to be treated for hepatitis is in need of an anti-inflammatory drug." *Id.*, at 9.

Applicants traverse. A finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and content of the prior art, the differences between the invention and the prior art, the level of ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d

1385 (2007). Both the suggestion of the claimed invention and a predictable expectation of success must be in the prior art, not in the disclosure of the claimed invention. *In re Dow Chem. Co.*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). "Obviousness requires a suggestion of ***all*** limitations in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940, 1947 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974) (emphasis added). And, one common inquiry of *any* obviousness test post-*KSR* is whether a skilled artisan would have had a reasonable expectation of success to practice the claimed invention. *Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in* KSR International Co. v. Teleflex Inc., 72 Fed. Reg. 57,528.

The references of Bistrian and Akimoto are directed to different objectives. Akimoto is directed to structured lipids and their producing having omega-9 polyunsaturated fatty acids in the second position of the specific lipid being produced. In contrast, Bistrian is directed to a ***different*** active ingredient – omega-9 polyunsaturated fatty acid is not the active ingredient – for treating liver dysfunctions. Given the difference in objective, there can be no guidance to one of ordinary skill to have combined any of the elements, even if taught, into the combination presently claimed. Furthermore, absent such guidance, there also can be no predictable expectation of success.

First, the Office misconstrues Bistrian. The Office fails to consider Bistrian's teachings ***as a whole***. Bistrian teaches a treatment for clinical disorders characterized by depletion of metabolic energy sources. *See e.g.*, Abstract of Bistrian. Bistrian states, for example:

> There remains a need for an improved method of increasing energy levels of splanchnic tissue. Especially in transplant situations, organs have depleted energy stores and cannot de novo produce required metabolic energy.
>
> Accordingly, it is an object of the invention to provide an improved method for increasing ATP levels in patients suffering from a form of splanchnic disorder.
>
> ...
>
> The present invention generally relates to ***providing adenosine, or one of its related nucleosides***, in an enteral feeding regimen which enables splanchnic

> tissues to more rapidly generate ATP, or other related nucleotides, during or following shock or trauma, including post-transplant situations.

See Bistrian, col. 2, lines 35-42; col. 3, lines 63-68 (emphasis added). Additionally, Bistrian describes the "***effective***" component of the diet as adenosine. Bistrian fails to suggest omega-9 polyunsaturated fatty acids as the active ingredient. See for example:

> The invention includes a total enteral nutrition diet having nutritionally ***acceptable amounts*** of a lipid source, a protein source, a carbohydrate source, a vitamin source, and a mineral source, and an ***effective amount*** of adenosine to achieve normal metabolic levels of ATP and/or its precursors in ATP deficient organs of a recipient host.

Abstract of Bistrian (emphasis added). Bistrian's lipid component (including omega-9 fatty acids) does not function to treat liver dysfunctions. At best, Bistrian may teach using adenosine or related nucleotides as ***the active component*** to treat various splanchnic disorders. But no where in the reference are an omega-9 fatty acid or an omega-9-constituted fat as ***the active component*** suggested for the amelioration of liver diseases associated with hepatopathy.

The Office is reminded that a reference must be reviewed for what it teaches ***as a whole***. Following the Office's reasoning, Bistrian would have taught using disclosed protein sources (such as albumin, casein, soy partial protein hydrolysates or crystalline amino acids) or disclosed carbohydrates (such as simple monosaccharides, disaccharides, oligosaccharides, or complex carbohydrates) as active components to treat splanchnic disorders.[1] This conclusion is similarly unsubstantiated.

Second, and in contrast, Akimoto is directed to a production method for "an oil containing triglyceride in which medium chain fatty acids are bound to the 1- and 3-positions of the triglyceride and polyunsaturated fatty acid is bound to the 2 position." *See* Akimoto, Abstract. The resulting triglyceride may contain an omega-9 fatty acid bound at the 2 position. However, Akimoto does not suggest let alone teach any specific medical or therapeutic effect(s) of the resulting triglyceride or triglyceride-containing oil. At best, Akimoto suggest:

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[1] "Protein sources could be whole protein (e.g., albumin, casein, soy partial protein hydrolysates or crystalline amino acids. Carbohydrates could be simple monosaccharides, disaccharides, oligosaccharides, or complex carbohydrates." *See* Bistrian, col. 4, lines 63-67.

1) omega-3 fatty acids "have numerous physiological functions such as preventative effects on adult disease such as arteriosclerosis and thrombosis, an anticancer action and an action that enhances learning acquisition";

2) the omega-6 fatty acid dihomo-γ-linolenic acid "is expected to demonstrate precursor effects on type I prostaglandins, antithrombotic action, blood pressure lowering action, antidyskinetic action, anti-inflammatory action, delayed allergy inhibitory effects, skin protective action and anticancer action;" and

3) omega-9 fatty acids "are able to become precursors of the leucotriene 3 group in the body, and their physiological activity is the target of considerable expectation and reported examples of which include anti-inflammatory, antiallergic and anti-rheumatic action."

See id., ¶¶ [0004] and [0014]-[0015]. Akimoto does not suggest using an omega-9 fatty acid or an omega-9-constituted fat as the *active component* to ameliorate liver diseases associated with hepatopathy.

The Office's reliance upon *Kerkhoven* is unsupported given the above arguments. The Bistrian's composition and the oil composition of Akimoto do not serve a common purpose. Nor do they share the same active component(s). The Bistrian's composition, which contains adenosine or other related nucleosides as the active component, is used to increase energy levels of splanchnic tissue, *i.e.*, by increasing ATP levels. *See e.g.*, Bistrian, col. 2, lines 40-45. As discussed *supra*, Akimoto is directed to a production method for an oil containing a type of defined triglyceride having a polyunsaturated fatty bound at the 2 position. Akimoto does not suggest any specific medical or therapeutic effect(s) of the produced triglyceride or triglyceride-containing oil. At best, Akimoto may suggest that the produced triglyceride or triglyceride-containing oil can be used "in a food, beverage or pharmaceutical composition." *See Akimoto*, Abstract. Accordingly, *Kerkhoven* does not apply.

As discussed *supra*, Bistrian may teach using adenosine or related nucleotides (but not an omega-9 fatty acid or an omega-9-constituted fat) as ***the active component*** to treat various splanchnic disorders. However, Akimoto teaches that omega-9 fatty acids are metabolized to leucotrienes to exert the anti-inflammatory, anti-allergic, and anti-rheumatic actions. *See e.g.*,

Akimoto, ¶ [0015].[2] An ordinarily skilled in the art would not have been motivated to combine Bistrian and Akimoto, let alone that the combination would have reached the claimed methods—administering "an omega-9 unsaturated fatty acid or a compound having an omega-9 unsaturated fatty acid as a constituent fatty acid ***as an active component***" to ameliorate liver diseases associated with hepatopathy.

As discussed above, neither Bistrian nor Akimoto, nor the combination of the two, teaches or suggests using an omega-9 fatty acid or an omega-9-constituted fat as an active component to ameliorate liver diseases as claimed. The references when viewed alone or in combination fail to teach or suggest at least the above-identified claim element. Without all claim elements taught, there can be no reasonable expectation of success that the presently claimed methods would have worked predictably.

Based on the above arguments, no *prima facie* case of obviousness can be adduced with regard to the claimed methods. Claims 17-31 thus stands non-obvious over cited art. Claims 39-46 are similarly non-obvious for reciting using an omega-9 fatty acid or an omega-9-constituted fat as an active component to ameliorate liver diseases. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection and allowance of claims 17-31 and 39-46.

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[2] "[0015] Fatty acids of ω9 series polyunsaturated fatty acids such as 5,8,11-eicosatrienoic acid (20:3 ω9 series, to be referred to as Mead acid) and 8,11-eicosadienoic acid (20:2 ω9 series) are known to be present as one of the constituent fatty acids in animal tissue deficient in essential fatty acids. However, since they are only present in minute amounts, their isolation and purification has been extremely difficult. ***These polyunsaturated fatty acids are able to become precursors of the leucotriene 3 group in the body, and their physiological activity is the target of considerable expectation and reported examples of which include anti-inflammatory, antiallergic and anti-rheumatic action*** (Japanese Unexamined Patent Publication No. 7-41421). Thus, although there is similarly a need for the development of triglycerides in which medium-chain fatty acids are bound to the 1,3-positions and .omega.9 series polyunsaturated fatty acid is bound to the 2-position, the existence of oils and fats (triglycerides) having a high content of ω9 series polyunsaturated fatty acid is unknown, and there are no known findings whatsoever relating to the production of a triglyceride for that purpose." (emphasis added).

CONCLUSION

In view of the above arguments and amendments to the claims, Applicants submit that the claims are in condition for allowance and respectfully request reconsideration and timely allowance of the claims.

Should the Office have any questions or comments regarding Applicants' amendments or response, please contact Applicants' undersigned representative at (202) 842-8821. Furthermore, please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, or for Notice of Appeal, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully Submitted,

Date: July 2, 2010 By: _____

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